

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

##### Design

The study of the two-course clinical trial of 96 patients was randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

##### Settings and conduct

Candidates for laparoscopic cholecystectomy in Valiasr Hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for laparoscopic cholecystectomy, ASA class 1 and 2 , no history of mental illness and psychosis, no Parkinson's disease, motion sickness or history of chemotherapy, patients under general anesthesia, duration of surgery 60 to 150 minutes, lack of sensitivity to the drugs used, no hypertension and no vascular problems Exclusion criteria: patients without conscious consent, death of the patient

##### Intervention groups

Intervention group 1: 0.5 mg / kg ephedrine will be prescribed. (Made by Biotica Pharmaceutical Company)  
Intervention group 2: 0.05 mg / kg dexamethasone will be prescribed. (Caspian Tamin Company, Rasht - Iran)  
Intervention group 3: 1 mcg / kg dexmedetomidin will be prescribed. (Exir - Iran)

##### Main outcome variables

Nausea, vomiting, sedation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N151**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

##### Registration date

2021-02-21, 1399/12/03

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-05, 1399/12/15

##### Expected recruitment end date

2022-03-06, 1400/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

### Public title

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Candidate patients for laparoscopic cholecystectomy ASA class 1 and 2 No history of mental illness and psychosis No Parkinson's disease, motion sickness or history of chemotherapy Patients under general anesthesia Duration of surgery 60 to 150 minutes Lack of sensitivity to the drugs used No hypertension and no vascular problems

#### Exclusion criteria:

Patients without conscious consent Death of the patient

### Age

From **18 years** old to **60 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **96**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple individual randomization with random allocation with envelopes in 2 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study is clinical trial.Outcome evaluator and analyzer and participant are blind (double blind).Outcome evaluator and analyzer and participant don't aware from grouping.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2021-01-24, 1399/11/05

#### Ethics committee reference number

IR.ARAKMU.REC.1399.311

## Health conditions studied

### 1

#### Description of health condition studied

cholecystectomy

#### ICD-10 code

K91.86

#### ICD-10 code description

Retained cholelithiasis following cholecystectomy

## Primary outcomes

### 1

#### Description

Incidence of nausea

#### Timepoint

Recovery and 2, 4, 6, 12 and 24 hours after surgery

#### Method of measurement

Observation

### 2

#### Description

Vomiting

#### Timepoint

Up to 24 hours after surgery

#### Method of measurement

Score 0 to 4

### 3

#### Description

Severe nausea  
**Timepoint**  
Up to 24 hours after surgery  
**Method of measurement**  
Visual analog scale

**4**

**Description**  
Sedation  
**Timepoint**  
In recovery and 1, 2 and 4 hours after surgery  
**Method of measurement**  
Ramsay score

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**  
Intervention group 1: 0.5 mg / kg ephedrine will be prescribed. (Made by Biotica Pharmaceutical Company)  
**Category**  
Treatment - Drugs

**2**

**Description**  
Intervention group 2: 0.05 mg / kg dexamethasone will be prescribed. (Caspian Tamin Company, Rasht - Iran)  
**Category**  
Treatment - Drugs

**3**

**Description**  
Intervention group 3: 1 mcg / kg dexmedetomidin will be prescribed. (Exir - Iran)  
**Category**  
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**  
**Name of recruitment center**  
Valiasr hospital  
**Full name of responsible person**  
Dr Hesamodin Modir  
**Street address**  
Valiasr hospital, Valiasr squire  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176941  
**Phone**

+98 86 3222 2003  
**Email**  
modir.he@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**  
**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Alireza Kamali  
**Street address**  
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176941  
**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
alikalaliir@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Arak University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
empty  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Hesamedin Modir  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Valiasr Hospital, Valiasr squire, Shahid Shirodi street

**City**  
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**Province**  
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**Postal code**  
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modir.he@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Associate professor  
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Specialist  
**Other areas of specialty/work**  
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**Province**  
Markazi  
**Postal code**  
3814957558  
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modir.he@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dorsa Dalaei  
**Position**  
medicine student  
**Latest degree**  
A Level or less

**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Complex Payambar azam, Basij square, Sardasht, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
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**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
Dorsadalaiei@yahoo.com  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

When we publish article in journal

### When the data will become available and for how long

After the article is published

### To whom data/document is available

Researcher in university

### Under which criteria data/document could be used

If there are additional questions

### From where data/document is obtainable

Dr Hesamodin Modir

### What processes are involved for a request to access data/document

Correspondence should be made with professors and universities.

### Comments